

Application No. 10/603,397

REMARKS

Claims 10-12 are pending. Claims 10-12 had previously been indicated as being allowable in an Office Action mailed March 8, 2005, and were subsequently rejected in an Office Action mailed June 14, 2005. No amendments have been made. Applicants hereby request further examination and reconsideration of this Application.

35 U.S.C. § 103 Rejection

In the Office Action of November 1, 2005, claims 10-12, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent No. H6-233772 to Morita. The Applicants have previously submitted a certified English translation of this Japanese reference. Applicants respectfully traverse this rejection.

When applying 35 U.S.C. § 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

See MPEP 2141.II, "Basic Considerations Which Apply to Obviousness Rejections", citing Hodosh v. Block Drug Co., 229 USPQ 182 (Fed. Cir. 1986).

In the Final Office Action of November 1, 2005, the application of 35 U.S.C. § 103 to claims 10-12 fails the required tenets of substantiating an obviousness rejection in every instance.

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Morita Has No Teaching or Suggestion of Application to "Living Tissue"

In its most basic form, the present invention is directed to a staple for use with wounds in living tissue (pending claims 10-12 and throughout the originally filed application including the Field of the Invention, Summary of the Invention, Detailed Description of the Preferred Embodiments; Claims; and Abstract). Morita never contemplates, teaches or suggests the use of a staple in "living tissue" as required by the claimed invention. On the contrary, Morita is directed solely to a suturing device for corpses or "dead tissue," especially in the context of corpses for which an autopsy has been performed. Morita specifically discusses examples of how the closure requirements for dead tissue in corpses subject to an autopsy are different than in a surgical context:

(2) Unlike surgery, in the case of an autopsy it is better if the conditions are such that there is only a short time required to close incision 28 before cremating the autopsied body 20. Especially with an autopsy of a corpse, because the autopsied body is gently laid to rest *and does not experience any substantial external force...*

Morita, [para. 0012] (emphasis added)

Contrary to the unsupported assertion in the Office Action [para. 2] that "[t]he staple of Morita is fully capable of being used in any kind of tissue (living/non-living)," it is respectfully submitted that Morita itself highlights significant differences between these two kinds of tissue and provides absolutely no teaching or suggestion for using the staple of Morita in living tissue. This aspect of the claimed invention as a whole cannot be swept aside by an unsupported assertion that a prior art reference would somehow be applied by a person of ordinary skill in the art in a context that is expressly distinguished from the context of that prior art reference. To do so violates both the first and second tenets of a proper obviousness rejection which require that both the inventions and the prior art references must be considered for their teachings as a whole.

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It is respectfully submitted that the claimed limitation of "living tissue" is not a mere recitation of intended use as alleged in the Office Action, but instead results in very different structural and functional requirements for the different contexts of living tissue vs. dead tissue. The structural and functional limitations of the claimed staple corresponding to these different structural and functional requirements are expressed in the claim language of claims 10-12 with respect to the manner in which the shoulder portions of the claimed staple are constructed.

Morita Is Not Capable of Performing Claimed Limitation

It is respectfully submitted that the assertions in the Office Action that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim," [para. 2] and that "the staple of Morita only needs to be capable of performing the claimed limitation" [para. 3] are both incorrect statements of the proper tests for obviousness and ignore the express language of the claimed invention. While these statements might have some applicability in the context of an anticipation rejection, the claimed inventions stand rejected as being obvious over Morita, not anticipated by Morita.

Morita discloses suturing device 19 as being manufactured of materials such as rigid plastic that are combustible. Morita [par. 0010]. Contrary to the assertions in the Office Action, a staple made of a rigid material such as the rigid plastic as taught by Morita would break under the application of a lateral force on the needle stem parts 12 and 13, most often in the middle of the backspan connecting stem 11. Even if the staple of Morita did not break, a person skilled in the art would understand that the structure of the Morita staple would not bend at the shoulder

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portions, but rather would bend in the middle of the backspan connecting stem 11 because there is more rigid physical material at the shoulder portions.

The reference in the Office Action [para. 5] to Morehouse (US 718649) as standing for the proposition that the staple would spread outwardly “[b]ecause of the angle present by the cleat when the staple is driven into tissue,” is inapposite to the claimed invention which requires that the structure of the staple transition to “a second deformed position at a second time *subsequent* to the insertion time.” Based on this argument in the Office Action, it is respectfully submitted that Morita actually teaches away from the present invention by teaching that the staple spreads outwardly at the insertion time, and not subsequent to the insertion time.

Morita Admittedly Has No Teaching of Use of a Bioabsorbable Material

Although claims 10-12 stand rejected for obviousness, not anticipation, Morita was the only reference cited in support of this rejection. The Office Action expressly admits that “[i]t should be noted that Morita fails to teach that the staple is bioabsorbable.” [para. 8]. Instead, the argument is made that the selection of bioabsorbable as a material for the staple of Morita would have been a matter of design choice for a person of ordinary skill in the art, citing *In re Leshin*, 125 USPQ 416. “Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” *In re Werner*, 55 USPQ 2d 1313 (Fed. Cir. 2000).

Applicants certainly do not contend that that the use of a bioabsorbable material is unknown to those of skill in the art of surgical staples and clips. However, the rejection is utterly devoid of any discussion relative to the motivation, desirability and obviousness of modifying

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the combustible staple disclosed by Morita to use a bioabsorbable material. Moreover, the assertion that selection of material would have been a matter of design choice impermissibly ignores both the express teaching of Morita and the basic facts about bioabsorbable materials.

Morita discloses suturing device 19 as being manufactured of combustible materials such as rigid plastic. Morita [para. 0010]. At no point, does Morita ever discuss bioabsorbable materials because there could be no plausible reason to use such materials in dead tissue. In fact, Morita teaches away from the use of bioabsorbable materials by suggesting the suturing device 19 be manufactured at low cost by a combustible plastic molding process. Morita [par. 0012(3)]. The significantly more expensive costs of bioabsorbable materials as compared to other kinds of materials for staples is recognized and discussed in the present application as filed at page 11, lines 8-16. It is difficult to comprehend how one of skill in the art would be motivated as a matter of design choice to use a bioabsorbable polymer, which typically costs on the order of hundreds of dollars per kilogram, in a combustible, autopsy staple that is preferably in place only a short time before cremation. Morita [para. 0012(2)]. This assertion is even more difficult to understand in view of the overall teaching of Morita that the characteristic of the material chosen for the staple is that the material be combustible, not bioabsorbable. Because the staple of Morita is used in dead tissue, as compared to living tissue as required by the claimed invention, the cellular processes normally relied upon for living tissue to absorb a bioabsorbable material will not be present. Morita teaches that the staple will be necessarily destroyed during cremation, therefore there is absolutely no motivation or reason for a person of skill in the art to attempt to make use of the non-existent cellular processes of living tissue to absorb the staple of Morita.

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Suggested Motivation for Modifying Morita Relies On Impermissible Hindsight

It is respectfully submitted that the arguments for modifying Morita set forth in the Office Action are the result of an unsupportable bootstrap combination of two different assumptions: (i) that the staple of Morita should be used in living tissue, and (ii) that the staple of Morita should be made of a bioabsorbable material, neither of which is explicitly or implicitly taught or suggested within Morita. For the reasons previously set forth, neither of these assumptions is valid by itself. More importantly, it is respectfully submitted that the only suggestion or motivation for even attempting to put together the bootstrap combination of these two assumptions is the impermissible use of the hindsight and teaching afforded by the present invention.

Arguments in the Office Action With Respect to Dependent Claim 11

In setting up the arguments as to independent claim 10, it is asserted in the Office Action that "[b]ringing the split tissue back together would cause a tension pulling on a staple used to bring the cut back together." [para. 4]. The force as hypothesized by this argument would be a pair of opposed forces pressing outwardly on each stem (leg) 12, 13 of the staple of Morita. In the argument with respect to dependent claim 11, it is asserted that there would be a "force applied to pull the cleat away from the arm." [para. 9]. In order to pull the cleat away from the arm using the tension from the split tissue, it is necessary that the staple first transition so that the force is pulling outwardly on the cleat instead of pushing inwardly. As discussed previously, there is absolutely no suggestion or teaching with Morita that the rigid autopsy staple could

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dynamically transition at the shoulder region without breaking nor is there any suggestion or teaching that the elbow region could similarly undergo a dynamic transition.

Arguments of Capability of Staple of Morita for Dependent Claim 12 Are Illusory

Morita expressly teaches a staple made of a rigid material. The limitations of dependent claim 12 require the shoulder portions be constructed of materials of a size, shape, volume, and material characteristics that the shoulder portions will generally resist lateral forces naturally exerted by opposed sides of the wound in living tissue for a period of at least 12 hours, after which the shoulder portions must then yield to these same lateral forces naturally exerted by the opposed sides of the wound. There is simply no teaching or suggestion of how the rigid combustible material of the Morita staple would respond by resisting the same forces for an initial period of 12 hours or more and then magically change and respond by deforming, but not breaking, in response to these forces during a period after that initial period. It is respectfully submitted that a person of skill in the art would understand that a rigid material will not behave in this manner, but would instead respond in a binary manner by either: (a) breaking relatively shortly after the application of the force, or (b) not deforming at all.

CONCLUSION

As set forth in the response dated August 15, 2005, independent claim 10 is addressed to a *dynamic* bioabsorbable staple that deforms "at a second time *subsequent to the insertion time in response to lateral forces naturally exerted by the opposed sides of the wound.*" Morita teaches a combustible suturing device for use during autopsies of corpses, i.e., within dead tissue. In the

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tissue of the deceased as described in Morita, there is no tissue healing, and as such, no suggestion, teaching, or disclosure of deformation of the suturing device in response to lateral forces naturally exerted by the opposed sides of the wound. Furthermore, Morita utterly lacks any disclosure with respect to deformation of the closure device where the shoulder portion of the staple is constructed such that the shoulder angle transitions from "a first position at insertion time" to "a second deformed position at a second time subsequent to the insertion time." Accordingly, Applicants respectfully request withdrawal of the rejection to independent claim 10, as well as dependent claims 11 and 12.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

  
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